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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,976	ALMARSSOO ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 13-16, and 19-23, drawn to topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms and compositions comprising the same, classified in class 514, subclass 23.

II. Claims 1, 3, 11-14, and 17-21, drawn to co-crystals or complexes of topiramate and additional agents, classified in class 514, subclass 23.

III. Claims 24-25, drawn to controlled release dosage forms of topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

IV. Claims 24-25 and 31-33, drawn to controlled release dosage forms of topiramate co-crystals or complexes, classified in class 514, subclass 23.

V. Claims 34 and 36-38, drawn to methods of treating or preventing seizures using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

VI. Claims 34-38 and 61, drawn to methods of treating or preventing seizures using topiramate co-crystals or complexes, classified in class 514, subclass 23.

VII. Claim 39, drawn to methods of treating or preventing tremors using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

VIII. Claims 39-40 and 61, drawn to methods of treating or preventing tremors using topiramate co-crystals or complexes, classified in class 514, subclass 23.

IX. Claims 41 and 43, drawn to methods of treating migraines using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

X. Claims 41-44 and 61, drawn to methods of treating migraines using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XI. Claims 45 and 47, drawn to methods of treating or preventing neuropathic pain using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XII. Claims 45-47 and 61, drawn to methods of treating or preventing neuropathic pain using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XIII. Claims 48 and 50-51, drawn to methods of treating or preventing cerebral function disorders using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XIV. Claims 48-51 and 61, drawn to methods of treating or preventing cerebral function disorders using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XV. Claim 52, drawn to methods of treating or preventing obesity or weight gain using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XVI. Claims 52-53 and 61, drawn to methods of treating or preventing obesity or weight gain using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XVII. Claims 54 and 56, drawn to methods of treating or preventing affective disorders using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XVIII. Claims 54-56 and 61, drawn to methods of treating or preventing affective disorders using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XIX. Claim 57, drawn to methods of treating or preventing cluster headaches using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XX. Claims 58 and 61, drawn to methods of treating or preventing cluster headaches using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XXI. Claim 59, drawn to methods of quitting smoking using topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XXII. Claims 60 and 61, drawn to methods of quitting smoking using topiramate co-crystals or complexes, classified in class 514, subclass 23.

XXIII. Claims 62-65, drawn to complex pharmaceutical dosages comprising topiramate salts, polymorphs, solvates, hydrates, dehydrates, anhydrous forms, or amorphous forms, classified in class 514, subclass 23.

XXIV. Claims 62-64 and 66-68, drawn to complex pharmaceutical dosage forms comprising topiramate co-crystals or complexes, classified in class 514, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the distinct products are not seen to be obvious variants. The various forms of dosages of group I include topiramate as the only agent and the products of group II include topiramate and an additional agent being complexed together or co-crystallized, which is not seen to be obvious in light of the single agent compounds/compositions.

Inventions I and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the distinct products are not seen to be obvious variants. The dosages of group I do not require a means for controlled release, and it would not seen to be obvious to incorporate a controlled release form into the compositions of group I.

Inventions I and IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use

together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the distinct products are not seen to be obvious variants. The various forms of dosages of group I include topiramate as the only agent and the products of group IV include topiramate and an additional agent being complexed together or co-crystallized, and additionally being in controlled release form, which is not seen to be obvious in light of the single agent compounds/compositions.

Inventions I and V-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as with any of the other processes of the remaining groups. It is noted that the conditions claimed to be treated/prevented in groups V-XXII are not seen to be related, i.e., obesity is not seen to be related to migraines, is not seen to be related to seizures, is not seen to be related to quitting smoking, etc.

Inventions I and XXIII-XXIV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are mutually exclusive. It is noted that the compositions of groups XXIII-XXIV are drawn to advanced pharmaceuticals comprising various wall cavities, drug layers, expandable layers, etc., which are not required by

the compositions of group I. A reference anticipating or rendering obvious the invention of group I may not necessarily anticipate or render obvious the invention of groups XXIII or XXIV, as such, a further search and consideration would be required.

Inventions II and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the distinct products are not seen to be obvious variants. The various forms of dosages of group III include topiramate as the only agent and additionally being in controlled release form, which is not seen to be obvious in light of the single agent compounds/compositions, and the products of group II include topiramate and an additional agent being complexed together or co-crystallized.

Inventions II and IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the distinct products are not seen to be obvious variants. The dosages of group II do not require a means for controlled release, and it would not seen to be obvious to incorporate a controlled release form into the compositions of group IV.

Inventions II and V-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as with any of the other processes of the remaining groups. It is noted that the conditions claimed to be treated/prevented in groups V-XXII are not seen to be related, i.e., obesity is not seen to be related to migraines, is not seen to be related to seizures, is not seen to be related to quitting smoking, etc.

Inventions II and XXIII-XXIV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are mutually exclusive. It is noted that the compositions of groups XXIII-XXIV are drawn to advanced pharmaceuticals comprising various wall cavities, drug layers, expandable layers, etc., which are not required by the compositions of group II. A reference anticipating or rendering obvious the invention of group II may not necessarily anticipate or render obvious the invention of groups XXIII or XXIV, as such, a further search and consideration would be required.

Inventions III and V-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as with any of the other processes of the remaining groups. It is noted that the

conditions claimed to be treated/prevented in groups V-XXII are not seen to be related, i.e., obesity is not seen to be related to migraines, is not seen to be related to seizures, is not seen to be related to quitting smoking, etc.

Inventions III and XXIII-XXIV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are mutually exclusive. It is noted that the compositions of groups XXIII-XXIV are drawn to advanced pharmaceuticals comprising various wall cavities, drug layers, expandable layers, etc., which are not required by the compositions of group III. A reference anticipating or rendering obvious the invention of group III may not necessarily anticipate or render obvious the invention of groups XXIII or XXIV, as such, a further search and consideration would be required.

Inventions IV and V-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as with any of the other processes of the remaining groups. It is noted that the conditions claimed to be treated/prevented in groups V-XXII are not seen to be related, i.e., obesity is not seen to be related to migraines, is not seen to be related to seizures, is not seen to be related to quitting smoking, etc.

Inventions IV and XXIII-XXIV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are mutually exclusive. It is noted that the compositions of groups XXIII-XXIV are drawn to advanced pharmaceuticals comprising various wall cavities, drug layers, expandable layers, etc., which are not required by the compositions of group IV. A reference anticipating or rendering obvious the invention of group IV may not necessarily anticipate or render obvious the invention of groups XXIII or XXIV, as such, a further search and consideration would be required.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Due to the complexity of the instant restriction requirement, no telephone call was made to applicants to request an oral election to the above restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss McIntosh

April 24, 2006

Shaojia A. Jiang

Supervisory Patent Examiner

Art Unit 1623